www.nytimes.com
The New York Times
ON THE WEB

June 10, 2002

Gaming the Drug Patent System

With high drug prices becoming an acrimonious part of the health care debate, attention has justifiably focused on the devious tactics used by some pharmaceutical companies to extend the patents of their best-selling drugs, forestalling competition from cheaper generics. These underhanded tactics must be stopped.

The issue arises because some drug companies have resorted to clever legal stratagems to extend the effective life of their patents beyond the 20 years originally granted to allow them to recoup the huge costs of developing a drug and make a reasonable profit. Some of these maneuvers take advantage of existing loopholes in the law; others appear downright fraudulent.

At least one method used by many companies to extend patents is both lawful and beneficial to the public. Any drug company can gain an extra six months of patent protection on a drug by conducting clinical studies in children to determine the best doses for young people. That added time can allow companies to rake in hundreds of millions of dollars more before the way is open for cheaper generics to drive prices down. But Congress deemed this a tradeoff worth making to ensure adequate testing of drugs for children, and many pediatric groups and children's advocates agreed.

Other tactics are clearly detrimental to the public good. In one approach, a company whose main patent on a drug is about to expire can win a reprieve by suing a potential generic competitor for infringing peripheral patents on packaging, dosing schedules or other secondary issues. Under a loophole in federal law, that automatically triggers a 30-month delay in the entry of the generic, no matter how frivolous the lawsuit against it may ultimately prove to be.

In another disreputable tactic, a company about to lose patent protection on a brand-name drug can simply pay a potential generic competitor millions of dollars not to produce the cheaper version of the drug. A federal judge has already ruled that one such agreement was "unlawful on its face."

These nefarious schemes are being challenged, as they should be, in the courts and in Congress. Consumer groups, state attorneys general and generic manufacturers have sued various drug companies for patent abuses. Last month, a Senate health subcommittee held hearings on a bill, co-sponsored by Charles Schumer of New York and John McCain of Arizona, that would close some of the biggest loopholes. It would, for example, eliminate the automatic 30-month delay triggered by a brand-name manufacturer's lawsuit and leave it

to the courts to decide whether such a stay was warranted. A companion measure is pending in the House.

How rampant the abuses may be is not yet clear. Timothy Muris, the Bush appointee who leads the Federal Trade Commission, complained at a Congressional hearing that some companies are trying to "game" the patent system, using tactics that have become "a very serious problem." His agency is conducting a study, due to be released this summer, that may shed more light on the dimensions of the problem. If the abuses are as widespread as consumer advocates expect, an even more vigorous campaign to curb them would be warranted.